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(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FRIEDRICH W. KUHNE

Appeal No. 95-4791
Application 08/034,849¹

HEARING: August 5, 1998

Before WINTERS, WILLIAM F. SMITH, and GRON, Administrative
Patent Judges.

GRON, Administrative Patent Judge.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

Introduction

¹ Application for patent filed March 19, 1993. Applicant claims the benefit under 35 U.S.C. § 119 of the March 19, 1992, filing date of Application P42 08 828.3 in the Federal Republic of Germany.

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This is an appeal under 35 U.S.C. § 134 of an examiner's rejection of Claims 1-13, all claims pending in this application. Claims 1-13 stand finally rejected under 35 U.S.C. § 103 as being unpatentable in view of the combined teachings of Sanosa G.M.B.H. (Sanosa), UK Patent Specification 481,732, published March 16, 1938; The Merck Index, 10th Edition, page 1236, Abstract No. 8465 (1983); Kuhne et al. (Kuhne I), EP-200,156, published November 5, 1986;² Kuhne et al. (Kuhne II), EP-200,157, published November 5, 1986;³ and the prior art described in appellant's specification. The examiner has withdrawn the final rejection of Claims 1-13 under 35 U.S.C. § 101 (Examiner's Answer (Ans.), page 2). Claims 1, 10 and 11 are representative of the subject matter claimed and read:

1. A method of parenterally treating HIV infections, comprising administering to a subject in need of such treatment an inhibition-effective amount of a chemically-stabilized chlorite matrix comprising an isotonic solution containing about 5 to about 100 mMol ClO_2^- per liter of isotonic solution.

10. A method according to claim 1, wherein the

² Canadian Patent 1,268,714, issued May 8, 1990, appears to be the English equivalent.

³ Australian Patent Specification 599,027, published November 6, 1986, appears to be the English equivalent.

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unbound HIV virus present in the subject is inactivated by the treatment thereby inhibiting infection of undamaged cells.

11. A method according to claim 1, wherein the concentration of T-cells and NK cells are increased after administration of said chlorite matrix.

The examiner appears to be satisfied by the evidence of record that (1) the method appellant claims meets the practical utility requirements of 35 U.S.C. § 101, and (2) the description of the claimed invention in the specification would have enabled one skilled in the art to make and use the full scope of the method claimed in the manner provided by the first paragraph of 35 U.S.C. § 112. We review the merits of the final rejection under 35 U.S.C. § 103 in that light.

Discussion

1. Claim interpretation

The claimed process of parenterally treating HIV infections requires parenteral administration of an inhibition-effective amount of a chemically-stabilized chlorite matrix comprising an isotonic solution containing about 5 to about 100 mMol ClO_2^- per liter of isotonic solution to a subject in need of treatment for HIV infections. We hold that the phrase "HIV infections" in appellant's claims means

"the various subsidiary forms of the HIV virus" (Specification (Spec.), p. 1, l. 9-10). Therefore, appellant's claims are limited to a method of treating the various subsidiary forms of the HIV virus by parenterally administering amounts of the chemically-stabilized chlorite matrix effective to inhibit one or more of the various forms of HIV virus to a subject infected by one or more of the various forms of HIV virus. It is to be understood that opportunistic infections associated with infections by one or more of the various forms of the HIV virus simultaneously may be treated by the method claimed. However, the claims require the step of administering amounts of a chemically-stabilized chlorite matrix to a subject infected by one or more of the various forms of the HIV virus in amounts effective to inhibit the HIV viral infection.

2. Prior art teaching

A. Sanosa, The Merck Index, and Acknowledgments

The examiner finds that Sanosa and The Merck Index teach stabilized chlorite solutions of the type utilized in appellant's claimed process for use as topical, surgical, and/or wound disinfectants and antiseptics (Ans., pp. 3-4). We need not dwell on the question whether the examiner erred

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in interpreting appellant's claims or clearly erred in finding identity between the stabilized hypochlorite solutions Sanosa and The Merck Index describe and the stabilized chlorite solutions employed in the processes appellant claims (Ans., pp. 7-8, bridging para.). Appellant's specification expressly states (Spec., p. 5, l. 27-34):

The chlorite matrix, designated as WF10 in the following experiments, was produced in accordance with Example 1 of [Kuhne,] U.S. 4,507,285[, patented March 26, 1985,] which is hereby incorporated by reference by the oxidation of a chlorite solution with hypochlorite, reaction with perborate or percarbonate and dilution with an isotonic solution of sodium chloride or an appropriate nutrient medium to the concentrations given in the following examples.

The examiner correctly finds that the "solution recited in claims 5-6 and 12-13 (set forth in U.S. . . . 4,507,285 incorporated by reference at page 5 of the instant specification), is taught as useful for sterilization, disinfection and therapy of viral infections (Patent (285), column 3, lines 35-55)" (Ans., p. 8).⁴ Appellant's

⁴ Column 3, lines 35-49, of U.S. 4,507,285 read:

The activated oxygen stabilized according to the invention, which is contained in a matrix of chlorite ions, can be used in various fields, for example, in medicine and in veterinary medicine,

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specification states (Spec., p. 2, l. 5-13):

DE-OS 32 13 389, United States Patent No. 4,507,285 and United States Patent No. 4,296,103, describe chemically-stabilized chlorite matrices which are suitable for an external or oral therapeutic use. Besides various bacterial infections, the external treatment of virus infections, such as herpes simplex and herpes zoster, is deemed possible in this manner but an intravenous administration for the treatment of HIV infections is not possible.

B. Kuhne I and Kuhne II⁵

Canadian Patent 1,268,714 (Canada) describes "the use of a composition consisting of an aqueous solution of a chemically stabilized chlorite matrix for intravenous and topical administration in tumor treatments" (Canada, p. 1, l. 13-16). Isotonic solutions of stabilized chlorite matrices

in cosmetics, for the sterilization of food and drinking water, and as feed additives. General areas of medical application are to be found in the fields of disinfectants and chemoprophylaxis. The stabilized activated oxygen according to the invention can especially be used, for example, for the treatment of skin diseases such as herpes simplex [sic], herpes zoster, acne or burns, or wound healing disorders or for macrophage and phagocyte stimulation. In particular, an arteriopathy and an alopecia areata can be influenced significantly. With melanomes [sic] significant remissions have been obtained.

⁵ We consider Canadian Patent 1,268,714 to be an English translation of EP-200,156 and Australia 599,027 to be an English translation of EP-200,157. We cite the English publications.

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are administered in conjunction with conventional radiotherapy and chemotherapy to influence the efficiency of conventional radio- and chemotherapeutics (Canada, p. 1, l. 27, to p. 2, l. 24). The stabilized chlorite matrices are said to influence the body's own defense mechanisms (Canada, p. 3, l. 29-31).

Australia 599,027 (Australia) describes "the use of an aqueous solution of a stabilized chlorite matrix for intravenous administration in infectious conditions caused by parasites, fungi, bacteria, viruses and/or mycoplasmas" (Australia, p. 2,

l. 1-5). At page 2, lines 16-22, Australia teaches:

It is known from the literature . . . that there is a close correlation between the extent of the oxidative response to phagocytosis and the ability to kill microorganisms intracellularly.

Australia proffers the results of in vitro tests on select bacterial infections which purportedly illustrate that stabilized chlorite matrices stimulates phagocyte activation and cellular immune responses in vivo (Australia, p. 2a, l. 19, to p. 6,

l. 26). The evidence to which Australia points purports to support its claims that effective amounts of aqueous solutions of a stabilized chlorite matrix with a chlorite concentration

of

12 to 72 $\mu\text{mol ClO}_2^-$ per ml may be administered intravenously to treat infectious conditions caused by parasites, fungi, bacteria, viruses and mycoplasmas (Australia, p. 2a, first para.).

3. Issues and Findings

The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should

be carried out and would have a reasonable likelihood of success, viewed in light of the prior art.

In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). "[T]he appealed claims must be considered in light of all the evidence, and the resulting decision, that the claimed invention would or would not have been obvious, is to be made in such light." In re May, 574 F.2d 1082, 1089, 197 USPQ 601, 607 (CCPA 1978).

The examiner argues that persons having ordinary skill in the art reasonably would have expected from prior art teachings as a whole that parenteral administration of isotonic solutions of chemically-stabilized chlorite would not only inhibit (1) virus infections of subjects infected with all types of viruses, and (2) retrovirus infections of

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subjects infected with all types of retroviruses, but also (3) the various subsidiary forms of the HIV virus infections in humans infected with the various subsidiary forms of the HIV virus. We disagree for the following reasons.

First, we find that the prior art direction to (1) topically administer stabilized chlorite solutions prior to, or in the course of, surgery as an anti-infectant, disinfectant, or antiseptic, (2) topically or intravenously administer stabilized chlorite solutions as an antitumor agent in conjunction with radio- or chemotherapy, and (3) intravenously administer stabilized chlorite solutions for the treatment of "infectious conditions caused by parasites, fungi, bacteria, viruses and/or mycoplasmas," reasonably would not have led persons having ordinary skill in the art to expect success in treating HIV viral infection by parenteral administration of stabilized chlorite solutions to an infected subject without some objective evidence indicative of potential success. The only objective evidence of potential success in parenterally treating HIV virus infection that the examiner presents relates to the treatment of subjects infected with bacteria or subjects undergoing radio- or chemotherapy for malignant tumors. The only objective

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evidence of success in treating virus infections that the examiner presents relates to the topical treatment of herpes simplex or zoster. In short, the prior art does not adequately support its broad allegations that viral infections as a whole and, more specifically, infection by the HIV virus, can be treated by intravenous administration of stabilized chlorite solutions. The prior art applied against the appealed claims creates no more than an "obvious-to-try" situation. See In re Eli Lilly & Co., 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990):

An "obvious-to-try" situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued. *See generally In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (defining obvious-to-try as when prior art gives "only general guidance as to the particular form of the claimed invention or how to achieve it").

Second, Kuhne II, U.S. 4,507,285 (incorporated by reference in this application), and the teaching of EP-200,155 summarized at page 2 of this specification, reasonably would have suggested that stabilized chlorite solutions act to inhibit infections by stimulating macrophage and phagocyte activity, activity generally associated with bacterial

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infections. See page 2, l. 22-27, of appellant's specification and page 1064, **phagocyte**, of Stedman's Medical Dictionary, 24th Edition, Williams & Wilkins, Baltimore, MD (1982)(attached).

Third, we find that the physiological activity of the HIV virus is sufficiently unpredictable and so distinct from that of bacteria that persons having ordinary skill in the art reasonably would not have expected to be able to successfully treat subjects infected by the HIV virus using a procedure found to be successful for treating bacteria. Little correlation between success in treating the HIV virus and success in treating other RNA viruses has been found. See the Discussion in In re Wright, 999 F.2d 1557, 1561-1564, 27 USPQ2d 1510, 1513-1515 (Fed. Cir. 1993).

Fourth, the art has long sought and continues to search for suitable means and methods for successfully treating infection by the HIV virus.

Fifth, appellant's specification cites prior art which purports to teach that chlorine dioxide-liberating chlorites generally had been presumed to attack red blood cells and therefore had been considered unsuitable for treating

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infections via parenteral administration (Spec., pp. 1-2, bridging para.).

Having weighed the evidence favoring unpatentability against all the evidence to the contrary, we find that the greater weight of the evidence directs us to reverse the examiner's rejection. We particularly note that, prior to the Examiner's Answer, the examiner steadfastly held that the evidence in appellant's specification would not have enabled one skilled in the art reasonably to expect to successfully use the method appellant presently claims. In that light, we fail to see how general prior art suggestions to parenterally treat parasite, fungi, bacteria, virus and/or mycoplasma infections with chlorite solutions, which are supported by far less evidence than is presented in appellant's specification, reasonably would have allowed persons having ordinary skill in the art to expect to successfully treat HIV virus infection by parenteral treatment of a subject infected with HIV virus with known chlorite disinfectants.

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4. Conclusion

We reverse the examiner's rejections of Claims 1-13 under

35 U.S.C. § 103.

REVERSED

SHERMAN D. WINTERS)	
Administrative Patent Judge))	
)	
)	
WILLIAM F. SMITH)	BOARD OF PATENT
Administrative Patent Judge))	APPEALS AND
)	INTERFERENCES
)	
TEDDY S. GRON)	
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